

Appln. No. 10/621,867  
Reply to Office action of August 9, 2005  
Response dated September 7, 2005

### **REMARKS**

This paper is submitted in response to the Office Action mailed August 9, 2005 for the above-identified patent application. The Examiner has issued a restriction requirement stating that the application allegedly contains claims that are directed to the following patentably distinct inventions:

Group I corresponding to claims 1-35 drawn to cells of the skin comprising a nucleic acid molecule that comprises target binding domains, spacer regions and trans-splicing sequences and a method of producing chimeric RNAs in skin cells;

Group II corresponding to claims 36-57 drawn to nucleic acids encoding target binding domains, spacer regions and trans-splicing sequence and eukaryotic expression vectors comprising such nucleic acids; and

Group III corresponding to claims 58 and 59 drawn to methods for correcting genetic defects and imaging gene expression of cells of the skin comprising the administration of nucleic acids comprising one or more target domains and sequences to be trans-spliced.

The Examiner states that Group II is related to Groups I and III as product and process of use because the nucleic acids of Group II can be used to make the skin cells of Group I or in the methods of genetic correction or imaging of gene expression of Group III. According to the Examiner, inventions are distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product; or (2) the product as claimed can be used in a materially different process of using that product. The Examiner alleges that a nucleic acid molecule of Group II has a materially different structure than a cell comprising a nucleic acid of Group I and the methods of Group III require

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consideration of genetic defects or an image of gene expression. In addition, the Examiner alleges that the inventions of Groups I and III have different, non-coextensive effects and they are not disclosed as capable of use together. Applicants respectfully traverse the restriction requirement. However, to be fully responsive, Applicants provisionally elect Group II corresponding to claims 36-57, as required under 37 C.F.R. 1.143, without prejudice to the prosecution of subject matter of non-elected claims in other patent applications.

There is clearly a structural and functional relationship between the claims of Groups I, II and III. The claims of Groups I, II and II are directed to either cells comprising PTMs, PTMs, or methods of using PTMs. Specifically, the claims of all three groups directly relate to pre-trans-splicing molecules (PTMs) with specific features, e.g., one or more target binding domains, a spacer region and a nucleotide sequence to be trans-spliced to the target pre-mRNA.

Furthermore, the nucleic acid molecules and vectors of Group II have no use independent from the ability to mediate *trans*-splicing reactions to produce a chimeric RNA molecule, as recited in the method claims of Group III. Moreover, the claimed cells of Group I are not used in a materially different process. Thus, the process for using the claimed product cannot be practiced with another materially different product and the product as claimed cannot be used in a materially different process.

Moreover, Applicants respectfully direct the Examiner's attention to the claims of U.S. Patent No.: 6,280,978 ("the '978 Patent"), a patent containing subject matter related to that of the present invention. A review of the claims issued in the '978 patent demonstrates that the Patent and Trademark Office had previously determined that claims to compositions capable of targeting binding to a pre-mRNA and methods for producing a chimeric RNA molecule in a cell utilizing such compositions were considered a single invention.

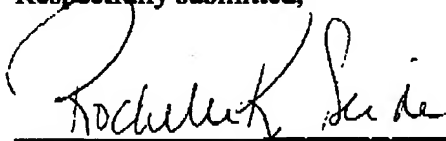
Appln. No. 10/621,867  
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Finally, as stated above, the claims of all three groups directly relate to pre-trans-splicing molecules (PTMs) with specific features, e.g., one or more target binding domains, a spacer region and a nucleotide sequence to be trans-spliced to the target pre-mRNA. "If the search and examination of an entire application can be made without serious burden, the Examiner *must* examine it on the merits, even though it contains claims to distinct or independent inventions." MPEP 803 *emphasis supplied*. Since the subject matter encompassed by the pending claims of Groups I, II and III are clearly related, Applicants respectfully submit that there would not be an undue burden to search and examine the claims of the application.

Applicants believe that no additional fees are required in connection with this response. However, if additional fees are required, the Commissioner is hereby authorized to charge any additional payment to Deposit Account No. 01-2300, referencing Docket Number 027705.00014.

In view of the foregoing, Applicants respectfully request that Examiner withdraw the restriction requirement.

Respectfully submitted,



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